K043454

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

MAR 2 1 2005

Medicomp, Inc.
7845 Ellis Road
Melbourne, Florida 32904

Date Summary Prepared: September 16, 2004

Contact: Mr. Michael Thomas

2. **Name of the Device:**

CardioPAL AI with Diogenes SV (CardioPAL SV) Model PM410

3. **Predicate Device Information:**

K#981119, CardioPAL (Model PM20) Event/Loop Recorder, Medicomp, Inc.

4. **Device Description:**

The CardioPAL AI with Diogenes SV (CardioPAL SV) Model PM410, is a small, auto triggered, hand-held device, prescribed by physicians for patients who are experiencing symptoms that may be attributable to cardiac arrhythmia. Shortness of breath and palpitations are examples of these symptoms. This device may be worn for a period of days or weeks – whatever time is necessary to capture and record the ECG.

The device consists of the CardioPAL SV event monitor and patient cable. The device can be used with accessories, including a belt clip, lanyard, and PC interface cable.

5. **Intended Use:**

The CardioPAL AI with Diogenes SV (CardioPAL SV) Model PM410, is a pager-sized, hand-held or patient worn device designed specifically to record and transmit ambulatory ECG signals. The device can be worn for days or weeks, as

it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.

6. Comparison to Predicate Device:

The following comparison chart outlines similarities and differences between the subject device and the predicate device:

Features	Predicate Device CardioPAL (PM20)	Subject Device CardioPAL SV (PM410)
ECG Storage	20 Minutes	20 Minutes
On Board Analysis	No	Yes
ECG Input	Finger Electrodes 1 Channel 2 Wires	1 Channel 2 Wires 1 Channel 3 Wires 2 Channel 3 Wires 2 Channel 5 Wires
User Interface	Audio Beeper 2 LEDs 2 Buttons	Audio Beeper 2 Line x 16 Character LCD 3 Buttons
PC Interface	Trans-telephonic RS232	Trans-telephonic USB
Case	Plastic	Plastic
EC38 Type	Type 3	Type 3
Battery	2 N Cell	1 AA

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

All testing performed on the CardioPAL AI with Diogenes SV (CardioPAL SV) Model PM410 was derived from the risk assessment which evaluated the effects of the feature changes. Testing included IEC 60601-1, IEC 60601-1-2, and environmental and software validation testing.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The subject device, CardioPAL AI with Diogenes SV (CardioPAL SV) Model PM410, has indications for use as the predicate device, CardioPAL Model PM20. The bench testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. Thus, the CardioPAL AI with Diogenes SV

(CardioPAL SV) Model PM410, is substantially equivalent to the predicate device, the CardioPAL Model PM20.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Medicomp, Inc.
c/o Ms. Susan Goldstein-Falk
MDI Consultants
55 Northern Blvd., Suite 200
Great Neck NY 11021

Re: K043454
Trade/Device Name: Cardiopal AI with Diogenes SV (Cardiopal SV), Model PM410
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: MLO
Dated: March 10, 2005
Received: March 11, 2005

Dear Ms. Golstein-Falk:

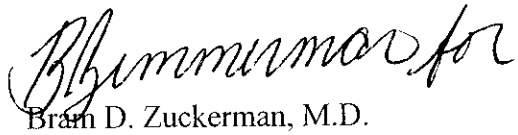
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment #1

510(k) Number (if known): K043454

Device Name: CardioPAL AI with Diogenes SV (CardioPAL SV) Model PM410

Indications For Use:

The CardioPAL AI with Diogenes SV (CardioPal SV) Model PM410, is a pager-sized, handheld or patient worn device designed specifically to record and transmit ambulatory ECG signals. The device can be worn for days or weeks, as it is intended for use by patients who are experiencing symptoms that are transient and infrequent in nature.

Prescription Use __X__
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use_____
(21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043454